## REMARKS

Claims 51 and 52 are pending in this application. Claims 51 and 52 have been rejected. Claims 51 and 52 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

### I. Withdrawn Rejections

Applicants acknowledge the withdrawal of the rejection of the claims under 35 U.S.C. 102(b) as being anticipated by Woodbury et al. ((2000) *J. Neurosci. Res.* 61:364-370).

### II. Rejection of Claims Under 35 U.S.C. §112

Claims 50 and 51 have been rejected under 35 U.S.C. 112, first paragraph, because it is suggested that the specification while being enabling for a method of inducing differentiation of an isolated human or rat marrow stromal cell into a pancreatic, insulin-producing cell, said method comprising contacting said isolated marrow stromal cell with at least one antioxidant, and then culturing in DMEM/20% FBS/10 ng/ml bFGF, does not reasonably provide enablement for a method of inducing differentiation of an isolated MSC from any species of animal comprising contacting isolated MSC with at least one antioxidant, thereby inducing differentiation of said isolated MSC into an endodermal/neuronal precursor cell and contacting said endodermal/neuronal precursor cell with any growth factor thereby producing an insulin secreting pancreatic islet cell. It is suggested that the teachings of Thomas et al. indicate that biological processes in cells are not

predictably conserved between species of animals. Applicants respectfully disagree with this rejection.

At the outset, it is respectfully pointed out that the Examiner has rejected claims 50 and 51 at page 3 of the Office Action. As claim 50 is no longer pending, Applicants have therefore assumed that this rejection is directed to claims 51 and 52.

Applicants respectfully disagree with the Examiner's suggestion that Applicants have not enabled the present invention. The specification discloses differentiation of at least two species of the claimed genus; the very two species of Thomas et al. which have been cited as responding unpredictably to IGFs, namely rat and human cells. Moreover, the instant cells contacted with a growth factor are distinct from the cells of Thomas et al. The cells contacted with the growth factor in accordance with the present invention are endodermal/neuronal precursor cells, wherein the cells of Thomas et al. are MSCs. In this regard, the teachings of Thomas et al. are not relevant to the response of the instant endodermal/neuronal precursor cells.

However, in the interest of facilitating the prosecution of this application and placing the claims in better form for consideration, Applicants have amended the claims to indicate that the cells of the claimed methods are rat or human, wherein endodermal/neuronal precursor cells are contacted with basic fibroblast growth factor to further the differentiate endodermal/neuronal precursor cells into insulin secreting pancreatic islet cells. Support for this amendment is found in the Examples, in particular at page 34 (lines 17-19) and page 36 (lines 1-7). In light of this amendment and accompanying remarks it is

respectfully requested that this rejection be reconsidered and withdrawn.

Claim 51 has also been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is suggested that the growth factor recited in the claim does not induce an insulin secreting pancreatic islet cell, rather it induces a marrow stromal cell to differentiate into one. To clarify the outcome of the claimed method, Applicants have amended claim 51 to indicate that the method results in the differentiation of an isolated marrow stromal cell into an insulin secreting pancreatic islet cell

**III. Rejection of Claims Under 35 U.S.C. §102**

Claims 51 and 52 have been rejected under 35 U.S.C. 102(e) as being anticipated by Sanchez-Ramos et al. (U.S. Patent No. 6,528,245). It is suggested that Sanchez-Ramos et al. teach obtaining bone marrow from mouse femurs or from human bone marrow aspirates; washing and centrifuging the cells; resuspending the cells in growth medium consisting of DMEM supplemented with 2 mM glutamine, 0.001% beta-mercaptoethanol, non-essential amino acids and 10% horse serum; and replating the cells after a 1:2 or 1:3 dilution with the addition of EGF or PDGF. It is suggested that while Sanchez-Ramos et al. are silent to the production of insulin-secreting pancreatic cells, the method of Sanchez-Ramos et al. would be expected to produce such cells. Applicants respectfully traverse this rejection.

The claims as currently presented recite contacting marrow stromal cells with an antioxidant followed by basic fibroblast

growth factor. While Sanchez-Ramos et al. suggest the use of EGF and PDGF, the claimed methods are neither taught nor suggested Sanchez-Ramos et al. Accordingly, this reference cannot be held to anticipate the instant methods. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

**IV. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

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